

Remarks

After amendment, claims 40, 51-56 and 66 remain pending in the present application. Claims 40, 53 and 55 have been amended. Claims 57-65 and claims 1-39 have been cancelled previously *without prejudice*. Claim 66 was previously amended. Support for the amendment to the claims can be found throughout the originally filed application and claims. Support for the addition of kidney cancer to claim 40 is found in the specification at page 11, in line 5. No new matter has been added by way of this amendment.

Applicants note that any subject matter which is cancelled herein, including any subject matter canceled from previously pending claims is made *without prejudice* in order to give Applicant a chance to consider filing any one or more divisional/continuation applications to seek allowance of that subject matter. The present amendments have been made to expedite allowance of the instant application and in particular, to address the enablement issue associated with cancers that are other than solid tumors. The presently pending claims are now directed to the use of the compounds as claimed in treating solid tumors and cancers as otherwise set forth in the claims. The treatment of the claimed tumors/cancers as set forth in the claims is consistent with the activity of the claimed compounds as anti-angiogenesis agents. The accompanying declaration of Dr. Jack Arbiser is enclosed in support of the enablement of the present invention.

Rejections

The Examiner has objected to or rejected the previously pending claims 40, 51-56 and 66 (note that the Examiner did not specifically reject claim 66, although Applicants, in order to advance prosecution of the present application, treat previously pending claim 66 as if it had been rejected) variously under 37 C.F.R. §1.75(c) and 35 U.S.C. §112, first and second paragraphs for the reasons which are stated in the June, 2010 office action on pages 2-9. Applicants respectfully submit that the presently pending claims are in

S.N. 10/502,080

5

B40-002.Amendment/Response 9-10

conformance with the requirements of 37 C.F.R. and 35 U.S.C. and are in condition for allowance for the reasons which are presented hereinbelow.

The Objection to Claims 50 and 51 Under 37 C.F.R. §1.75(c)

The Examiner has rejected previously pending claims 50 and 51 as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, the Examiner contends that each of claims 50 and 51 just repeat the identical options for the tumor and cancer, respectively, which are recited by amended claim 40. Applicants respectfully traverse the Examiner's rejection inasmuch as claims 50 and 51 each are directed to the treatment of tumors and/or cancer which are fewer than those which are set forth in amended claim 40. Thus, each of claims 50 and 51 is narrower than claim 40 and consequently, of completely proper form. It is respectfully submitted that claims 50 and 51 are now properly dependent on amended claim 40 and Applicants respectfully request the Examiner withdraw her rejection to claims 50 and 51 on these grounds.

The §112, Second Paragraph Rejection

The Examiner has rejected previously pending claims 52 and 53 under 35 U.S.C. §112, Second Paragraph for the reasons which are presented in the June, 2010 office action on page 9. The basis of the rejection is that claims 52 and 53 included kidney cancer in the cancer species which were presented in those claims, but claim 40, the independent claim upon which claims 52 and 53 depend, did not include kidney cancer. Applicants have addressed this issue by amending claim 40 to include kidney cancer, thus obviating the rejection made by the Examiner on these grounds. Applicants respectfully submit that with the amendment to claim 40, claims 52 and 53 now fully comply with the requirements of 35 U.S.C. §112, Second Paragraph.

The §112, First Paragraph Rejection

The Examiner has rejected/objected to previously pending claims 40-66 under 35 U.S.C. §112, first paragraph as being non-enabled for tumors and cancers which are presently claimed in the instant application as stated in the office action on pages 3-6. In particular, the Examiner indicates that the pending claims are directed to the treatment of a number of tumors and cancer for which enablement of the present invention is not provided. In response, Applicants attach hereto the declaration Dr. Jack L. Arbiser, M.D., Ph.D. in support of patentability of the present invention. Dr. Arbiser, who has extensive experience in cancer/tumor chemotherapy provides evidence that the presently claimed compounds are anti-angiogenesis inhibitors and as such, display an activity which is consist with the generic therapy of tumors and cancer. Based upon the enclosed declaration of Dr. Arbiser, Applicants respectfully submit that the presently claimed invention is enabled and therefore, patentable.

It is noted that the solenopsin compounds which are set forth in the presently claimed methods exhibit exceptional activity as inhibitors of phosphatidylinositol-3 kinase, and consequently, both directly and indirectly inhibit angiogenesis, which is critical for tumor/cancer growth and elaboration. Dr. Arbiser presents evidence in the form of two papers from his laboratory, in particular, Arbiser, et al, *Blood*, 15 January 2007, Volume 109, Number 2, pages 560-565 and Park, et al., *Journal of Infectious Diseases*, 15 October 2008, 198, 1198-201, attached hereto, which evidence that solenopsin is an effective inhibitor of phosphatidylinositol-3 kinase. By virtue of that inhibition which is implicated in both the direct and indirect inhibition of angiogenesis and the fact that inhibition of angiogenesis is consistent with favorable therapeutic outcome in a variety of tumors and cancer, Dr. Arbiser concludes that it is his expectation as a person of extraordinary experience and skill in cancer treatment modalities, that the present invention will be generally applicable for favorable therapeutic intervention and the treatment of a broad range of tumors and cancer.

S.N. 10/502,080
B40-002.Amendment/Response 9-10

7

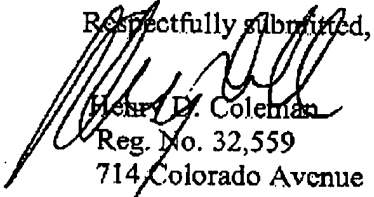
Based upon the declaration of Dr. Arbiser, Applicants respectfully submit that the presently claimed invention meets the requirements of 35 U.S.C. §112, first paragraph. No other rejections of the previously pending claims were made by the Examiner.

For all of the reasons which are set forth hereinabove, Applicants respectfully submit that the application is in condition for allowance and early action resulting in allowance of the instant application is earnestly solicited.

No fee is due for the presentation of this amendment. A petition for an extension of time is enclosed as is authorization to charge the petition fee of \$65 to Deposit Account 04-0838. Please charge any fee due or credit any overpayment previously made to Deposit Account No. 04-0838.

Dated: September 30, 2010

Respectfully submitted,


Henry D. Coleman
Reg. No. 32,559
714 Colorado Avenue
Bridgeport, Connecticut 06605
(203) 366-3560

Certificate of Facsimile Transmission

I hereby certify that this correspondence is being sent by facsimile to Examiner Brian M. Bullock, in Group Art Unit 1612 of the United States Patent Office in Alexandria, VA 22312-1450 on October 4, 2010.


Henry D. Coleman, Reg. No. 32,559

S.N. 10/502,080

B40-002.Amendment/Response 9-10

8